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August 12, 2010

The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
United States Senate

The Honorable Henry A. Waxman
Chairman
The Honorable Joe L. Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Sander M. Levin
Acting Chairman
The Honorable Dave Camp
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare and Medicaid Programs; Electronic Health Record Incentive Program*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), entitled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program” (RIN: 0938-AP78). We received the rule on July 13, 2010. It was published in the *Federal Register* as a final rule on July 28, 2010, with a stated effective date of September 27, 2010. 75 Fed. Reg. 44,314.

This final rule implements the provisions of the American Recovery and Reinvestment Act of 2009 that provide incentive payments to eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) participating in

Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified electronic health record (EHR) technology.¹ The rule specifies the initial criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment; calculation of the incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs, eligible hospitals, and CAHs failing to demonstrate meaningful use of certified EHR technology; and other program participation requirements.

Enclosed is our assessment of the CMS's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review of the procedural steps taken indicates that CMS complied with the applicable requirements.

If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Ann Stallion
Program Manager
Department of Health and
Human Services

¹ Pub. L. No. 111-5, §§ 4001–4201, 123 Stat. 115, 467–494 (Feb. 17, 2009).

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
"MEDICARE AND MEDICAID PROGRAMS;
ELECTRONIC HEALTH RECORD INCENTIVE PROGRAM"
(RIN: 0938-AP78)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) analyzed the costs and benefits of this final rule. CMS estimates that the total cost to the Medicare and Medicaid programs will be \$9.7 billion in transfers under a low scenario, and \$27.4 billion under a high scenario, over a 10-year timeframe. In its analysis, CMS assumes that benefits to the program would accrue in the form of savings to Medicare, through the Medicare eligible professional payment adjustments. At this time, CMS is unable to quantify the expected qualitative benefits. However, CMS did identify benefits for eligible hospitals and professionals including reductions in medical recordkeeping costs, reductions in repeat tests, decreases in the length of stays, and reduced errors. CMS also identified benefits to society, including improved quality of care, better health outcomes, and more efficient delivery of health care.

(ii) Agency actions relevant to the Regulatory Flexibility Act, 5 U.S.C. §§ 603-605, 607, and 609

CMS determined that this final rule will create a significant impact on a substantial number of small entities and therefore prepared a Regulatory Flexibility Analysis. CMS discussed the number of small entities and alternatives considered and concluded that, while economically significant, the net effect of this rule on individual providers will be negative over time except in very rare cases. CMS also analyzed the effect of this final rule on small rural hospitals and determined that any impacts arising from implementation of certified electronic health record technology in a rural hospital would be positive, with respect to the streamlining of care and the ease of sharing information with other eligible providers to avoid delays, duplication, or errors.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

CMS determined that this final rule imposes no substantial mandates on states because the program is voluntary for states and states offer incentives at their option.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

CMS published a proposed rule on January 13, 2010. 75 Fed. Reg. 1844. CMS received comments on this proposed rule, to which it responded in the final rule.

Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520

CMS identified 60 information collection requirements under the Act in this final rule. These information collection requirements have or will be submitted to the Office of Management and Budget (OMB) for review. CMS estimates that they will have a total annual burden of 6,344,458 hours for a total cost of \$42,781,944,348 in 2011 and 6,175,290 hours for a total cost of \$9,966,366,443 in 2012.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of sections 1302 and 1395hh of title 42, United States Code.

Executive Order No. 12,866 (Regulatory Planning and Review)

CMS determined that this final rule is economically significant because it is anticipated to have an annual effect on the economy of \$100 million or more.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication.